

JUL 19 2002

RE: 510(k): DEVICE MODIFICATION, ESOPHAGEAL Z-STENT WITH DUA
ANTI-REFLUX VALVE (K011591)

510(k) Summary of Safety & Effectiveness

Submitted By: Wilson-Cook Medical Inc.
4900 Bethania Station Road & 5951 Grassy Creek Blvd.
Winston-Salem, NC 27105

Device Description: The Esophageal Z-Stent with Dua Anti-Reflux Valve is a non-sterile, disposable device, used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistula. The product line includes Coated Metal Expandable stents in varying lengths and components to facilitate stent delivery.

Trade Name: Esophageal Z-Stent with Dua Anti-Reflux Valve

Classification Name/Code: Prosthesis, Esophageal/ 79 ESW

Classification: FDA has classified similar devices as Class II as per 21 CFR §878.3610 This device falls within the purview of the General and Plastic Surgery Device Panel.

Common/Usual Name: Esophageal Prosthesis

Establishment Registration Number: 1037905

Sterility: The Esophageal Z-Stent with Dua Anti-Reflux Valve is a non-sterile, disposable device.

Performance Standards: Performance standards applicable to Esophageal Prostheses have not been established by the Food and Drug Administration.

Intended Use: Used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistula.

Predicate Device(s):

Predicate Device	Manufacturer	Document Control Number
Covered Esophageal Z-Stent	Wilson-Cook Medical Inc.	K920218
Wilson-Cook Colonic Z-Stent	Wilson-Cook Medical Inc.	K990034

Substantial Equivalence:

The modified Esophageal Z-Stent with Dua Anti-Reflux Valve is substantially equivalent to the referenced predicate devices in that it is similar or identical with respect to technological characteristics, materials of construction and intended use.

RE: 510(k): DEVICE MODIFICATION, ESOPHAGEAL Z-STENT WITH DUA ANTI-REFLUX VALVE (K011591)

510(k) Summary of Safety & Effectiveness (continued)

Characteristic	Esophageal Z-Stent with Dua Anti-Reflux Valve[Subject of "Special" 510(k)]	Predicate Wilson-Cook Coated Esophageal Z-Stent (K920218)	Predicate Wilson-Cook Colonic Z-Stent (K990034)
Intended Use	Used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistula.	Used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistula	Used to maintain patency of malignant colonic strictures in patients having high operative risk and/or advanced disease.
Sterility	Non-Sterile, Disposable	Non-Sterile, Disposable	Non-Sterile, Disposable
Prostheses Configuration	Metal expandable Z-Stent Fully and Partially Coated	Metal expandable Covered Z-Stent	Metal expandable Z-Stent
Introduction System	Radiopaque coaxial catheter, Dilator Tip, Loading Funnel, Locking Ring, Thumb Ring w/String, Guiding Catheter and Wire Guide	Radiopaque coaxial catheter, Wire Guide	Radiopaque coaxial catheter, Dilator Tip, Loading Funnel, Locking Ring, Thumb Ring w/String, Guiding Catheter and Wire Guide
Stent Construction	Stent: Stainless Steel, Suture, Solder Coating: Polyurethane	Stent: Stainless Steel, Suture, Solder Coating: Polyurethane	Stent: Stainless Steel, Suture, Solder Coating: N/A
Stent Sizes	25 mm flared distal ends, 18 mm shaft Lengths: 8-14 cm	18, 21 & 25 mm flared distal ends, 15, 18 mm shaft, Lengths: 6-14 cm	35 mm flared distal ends 25 mm shaft Lengths: 4-12 cm

Biocompatibility: Reasonable assurance of biocompatibility for the patient contacting materials has been established through an extensive history of use in similar patient contacting medical devices and as applicable biocompatibility test results.

Design Control/Risk Analysis/Design Verification/Validation:

Design Control, Risk Analysis, Design Verification and Validation activities for the subject of this 510(k) have been conducted in accordance with all applicable internal procedures. The Design Control process employed is inclusive of the elements as stipulated by 21CFR § 820.30, as applicable to the project. The Risk Analysis performed identified the risks relative to the performance requirements, as specified by our internal procedure for Risk Analysis. The failure mode, effect of failure, severity, potential cause, rate of occurrence, design control element to eliminate, the potential to detect and our recommended actions were also documented. Additional testing to support the modifications to the predicate stent and introduction system has been conducted. During Design Verification and Validation, visual, dimensional and functional testing to ensure the performance and design integrity of this product line was conducted. All results obtained during our Design Verification and Validation met our predetermined acceptance criteria for this product line. Data from this testing has been documented and retained in our files.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2002

Ms. Paula Joyce
Vice President, QA/RA
Wilson-Cook® Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K011591
Trade/Device Name: Wilson-Cook® Esophageal
Z-Stent with Dua Anti-
Reflux Valve
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: 79 ESW
Dated: April 19, 2002
Received: April 22, 2002

Dear Ms. Joyce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011591

Device Name: Wilson-Cook Esophageal Z-Stent with Dua Anti-Reflux Valve

Indications for Use:

Used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistulas.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K011591

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter ☐
(Optional Format 1-2-96)